DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Smith and Nephew, Incorporated
Mr. Jason Sells
Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K081016
Trade/Device Name: Smith and Nephew, Inc. PROMOS Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: August 18, 2008
Received: August 19, 2008

Dear Mr. Sells:

This letter corrects our substantially equivalent letter of September 5, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081016

Device Name: Smith & Nephew, Inc. PROMOS® Reverse Shoulder System

Indications for Use:

The PROMOS Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

The humeral stem and body components are intended for cementless use.

The implants of the PROMOS Reverse Shoulder System are single use devices.

Mark N Millard

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081016

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K081016

Summary of Safety and Effectiveness
Smith & Nephew, Inc. PROMOS® Reverse Shoulder System

SEP - 5 2008

Contact Person and Address
Jason Sells
Project Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116
T (901) 399-5520

Date of Summary: July 14, 2008

Name of Device: Smith & Nephew, Inc. PROMOS® Reverse Shoulder System
Common Name: Shoulder Prosthesis
Device Classification Name and Reference: 21 CFR 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Device Class: Class II
Panel Code: Orthopaedics/87 HSD

Device Description
Subject of this Traditional 510(k) premarket notification is the PROMOS Reverse Shoulder System. The glenohumeral articulation of the Promos Reverse Shoulder is inverted – or reversed – when compared to traditional total shoulder prostheses. Unlike traditional total shoulder prostheses, the Promos Reverse Shoulder is designed so that the "ball" component of the shoulder is assembled to the glenoid baseplate and the "cup" component is assembled onto the humeral stem.

Mechanical and Clinical Data
A review of the mechanical and clinical data indicates that the implant components of the Promos Reverse Shoulder System are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Intended Use
The PROMOS Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

The humeral stem and body components are intended for cementless use.

The implants of the PROMOS Reverse Shoulder System are single use devices.

Substantial Equivalence Information
The substantial equivalence of the Promos Reverse Shoulder System is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – PLUS Orthopedics AG's PROMOS Modular Shoulder System (K063578), Depuy Orthopedics' DELTA CTA Reverse Shoulder Prosthesis (K021478), the Tornier S.A.S. Aequalis Reverse Shoulder Prosthesis (K041873), the Encore Medical Reverse Shoulder Prosthesis System (K041066), and Zimmer's Anatomical Inverse/Reverse Shoulder (K053274).